



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,084	05/25/2007	Keisuke Matsui	47635-0025-00-US (227671)	1575
55694 7590 07/16/2010 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209			EXAMINER O HARA, EILEEN B	
			ART UNIT 1638	PAPER NUMBER
			NOTIFICATION DATE 07/16/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBRIPDocket@dbr.com
penelope.mongelluzzo@dbr.com

Office Action Summary	Application No. 10/583,084	Applicant(s) MATSUI ET AL.	
	Examiner EILEEN B. O HARA	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-13 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-13 and 15-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/13/10</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1638

DETAILED ACTION

Status of Claims

Claims 1, 6-13 and 15-22 are pending in the instant application. Claims 1, 6-11, 15 and 16 have been amended and claims 2-5 and 14 have been canceled as requested by Applicant in the Paper filed May 13, 2010.

All claims are currently under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 13, 2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Withdrawn Objections and Rejections

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-13 and 15-22 remain rejected under 35 U.S.C. 102(b) as being anticipated by Mukerji et al, WO 99/64616, December 16, 1999, cited in IDS filed June 15, 2006.

Claims 1, 6-13 and 15-22 are drawn to an arachidonic-containing plant comprising introduced fatty acid synthetase genes associated with the biosynthesis of arachidonic acid, wherein the fatty acid synthetases associated with the biosynthesis of arachidonic acid are $\Delta 6$ desaturase, fatty-acid-chain elongase, *or* $\Delta 5$ desaturase, wherein the $\Delta 6$ desaturase is one of:

(claim 6) (a) a protein consisting of an amino acid sequence of SEQ ID NO: 1; and

(b) a protein, consisting of an amino acid sequence that has been modified by substitution, deletion, insertion, and/or addition of one or more amino acids of SEQ ID NO: 1, for catalyzing a reaction of introducing an unsaturated bond at position $\Delta 6$ of an aliphatic monocarboxylic acid, wherein the gene encoding the $\Delta 6$ desaturase is one of:

(claim 7) (c) a gene having a base sequence of SEQ ID NO: 2 as an open reading frame; and (d) a gene that hybridizes under stringent conditions with a gene of a base sequence complementary to a base sequence of a gene identified by SEQ ID NO: 2, and that encodes a protein which catalyzes a reaction of introducing an unsaturated bond at position $\Delta 6$ of an aliphatic monocarboxylic acid,

Art Unit: 1638

Wherein the fatty-acid-chain elongase is one of:

(claim 8) (e) a protein consisting of an amino acid sequence of SEQ ID NO: 3; and consisting of an amino acid sequence that has been modified by substitution, deletion, insertion, and/or addition of one or more amino acids of SEQ ID NO: 3, for catalyzing a reaction of elongating a carbon chain of an aliphatic monocarboxylic acid.

The arachidonic acid-containing plant as set forth in claim 1, wherein the gene encoding the fatty-acid-chain elongase is one of:

(claim 9) (g) a gene having a base sequence of SEQ ID NO: 4 as an open reading frame; and (h) a gene that hybridizes under stringent conditions with a gene of a base sequence complementary to a base sequence of a gene identified by SEQ ID NO: 4, and that encodes a protein which catalyzes a reaction of elongating a carbon chain an aliphatic monocarboxylic acid, wherein the $\Delta 5$ desaturase is one of:

(claim 10) (i) a protein consisting of an amino acid sequence of SEQ ID NO: 5; and (j) a protein, consisting of an amino acid sequence that has been modified by substitution, deletion, insertion, and/or addition of one or more amino acids of SEQ ID NO: 5, for catalyzing a reaction of introducing an unsaturated bond at position $\Delta 5$ of an aliphatic monocarboxylic acid, wherein the gene encoding the $\Delta 5$ desaturase is one of:

(claim 11) (k) a gene having a base sequence of SEQ ID NO: 6 as an open reading frame; and (l) a gene that hybridizes under stringent conditions with a gene of a base sequence complementary to a base sequence of a gene identified by SEQ ID NO: 6, and that encodes a protein which catalyzes a reaction of introducing an unsaturated bond at position A5 of an

Art Unit: 1638

aliphatic monocarboxylic acid, wherein the fatty acid synthetases associated with the biosynthesis of arachidonic acid, or the genes encoding the fatty acid synthetases are derived from *Mortierella alpina*, wherein the arachidonic acid producing step includes an expression suppressing step of suppressing expression of a $\Delta 5$ desaturase in a host by and RNAi method, wherein the plant comprises a plant cell, a plant tissue, a plant callus, a plant seed, a grown plant individual, or offspring of a plant individual having the same trait as the grown plant individual, wherein the plant comprises a soybean, arachidonic acid obtained from the arachidonic acid-containing plant, composition which comprises the arachidonic acid of claim 18, a food which comprises the arachidonic acid composition, arachidonic acid-containing plant preparation kit for preparing the arachidonic acid-containing plant of claim 1, comprising a recombinant expression vector including a promoter and genes encoding fatty acid synthetases associated with the biosynthesis of arachidonic acid, and further comprising a set of reagents for introducing the recombinant expression vector into a plant cell.

Mukerji et al teach making arachidonic-containing plants by transforming plants with genes from *Mortierella alpina*, wherein the genes are present in recombinant expression vectors comprising promoters and other regulatory elements, the genes are $\Delta 5$ desaturase, fatty-acid-chain elongase and $\Delta 6$ desaturase, using DNA expression constructs (abstract, page 2, 4, 5, 7, 8, 10, 12). These genes are operably linked to DNA encoding the genes (page 14), and promoter that may be a seed-specific promoter (pages 8 and 26).

Mukerji et al teach that the PUFAs produced and compositions comprising the arachidonic acids may be extracted (page 17-18), and that arachidonic acid and other PUFAs are important food sources (page 3). Also taught is that additional nucleic acid sequences may be

Art Unit: 1638

transformed into the plants to improve arachidonic acid production, such as sequences that inhibit $\Delta 15$ desaturase expression, such as antisense constructs (page 8). Plant parts are also taught and offspring of the transformed plants that produce arachidonic acid (page 5).

Therefore Mukerji et al anticipates the claims.

In page 4 of the the response filed May 13, 2010, Applicants write:

Claim 1 as amended recites, *inter alia*, an arachidonic acid-containing plant expressing at least A6 desaturase, fatty-acid-chain elongase, and A5 desaturase. At best, Mukerji may disclose a transgenic plant that (1) expresses a A5-desaturase gene, and (2) is capable of producing arachidonic acid. *See* Mukerji, Example 3, pages 22-23, and Table 1, page 25. Mukerji thus fails to disclose at least a plant expressing A6 desaturase and fatty-acid-chain elongase genes--the other two genes recited in amended claim 1.”

However, claim 1 recites:

“wherein the fatty acid synthetases associated with the biosynthesis of arachidonic acid are $\Delta 6$ desaturase, fatty-acid-chain elongase, or $\Delta 5$ desaturase”.

Therefore, claim 1 as amended only requires the introduction of one of the fatty acid synthetases, and not all three.

Allowable Subject Matter

Nucleic acid sequences encoding the proteins comprising the amino acid sequences of SEQ ID NOS: 1, 3 and 5, are free of the prior art.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara whose telephone number is (571) 272-0878. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1638

system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eileen B. O'Hara/
Primary Examiner
Art Unit 1638*-